

The opinion in support of the decision being entered today was *not* written for publication and is *not* binding precedent of the Board

Paper No. 25

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MICHAEL SUDGE

Appeal No. 1998-2521
Application No. 08/184,212

ON BRIEF

Before MCCANDLISH, Senior Administrative Patent Judge, MCQUADE and NASE, Administrative Patent Judges.

MCCANDLISH, Senior Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on an appeal from the examiner's final rejection of claims 1 through 33 and 37 through 48. The only other claims still pending in the application, namely claims 34, 35 and 49, have been allowed.

Appellant's invention relates to a holder for a medical tube such as an endotracheal tube. Claims 1 and 37, the only independent claims on appeal, define the invention as follows:

1. A medical tube holder apparatus comprising a one-piece flexible elongated strip clamp means configured transversely to engage frictionally about substantially the entire circumferential cross-section of medical tubes for oral and

nasal insertion having radii within a predetermined range, with opposing interlocking extremities accommodating said differing tube radii, and with opposing attaching means integral with said clamp means for affixing a harness means.

37. A medical tube holder apparatus comprising a one-piece flexible elongated strip to engage frictionally about substantially the entire circumferential cross-section of medical tubes for oral and nasal insertion, with opposing interlocking extremities of said strip and with opposing attaching means integral with said strip for affixing a harness means, wherein the said strip, exclusive of said interlocking extremities and said attaching means, is less than one centimeter thick.

As disclosed, the interlocking extremities are in the form of serrated male and female locking components 2, 3. The attaching means are in the form of ears 4.

A complete copy of the appealed claims is found in the revised appendix (Paper No. 20 filed on September 8, 1999) to the appeal brief. According to the remarks on page 2 of the examiner's supplemental answer (Paper No. 23 mailed December 6, 2000), the revised appendix contains a correct copy of the appealed claims.

The following references are relied upon by the examiner as evidence of obviousness in support of his rejections under 35 U.S.C. § 103:

Cheng	2,908,269	Oct. 13, 1959
Crosbie	5,069,206	Dec. 3, 1991
Austin	5,076,269	Dec. 31, 1991

Ohio Chemical Catalog, "White Opaque Plastic Endotracheal Tubes," page 40, (Date unknown)¹

The grounds of rejection are as follows:²

1. Claims 1 through 9, 19 through 24 and 37 through 48 stand rejected under

¹ Appellant does not argue that this catalog is not prior art.

² In the supplemental answer (Paper No. 23 mailed December 5, 2000) responding to our remand of July 17, 2000 (Paper No. 22), the examiner withdrew the rejection of the appealed claims under the first paragraph of 35 U.S.C. § 112, leaving only the § 103 rejections.

35 U.S.C. § 103 as being unpatentable over Crosbie in view of Austin and the Ohio Chemical Catalog (Page 40).

2. Claims 10 through 18 and 25 through 33 stand rejected under 35 U.S.C. § 103 as being unpatentable over the prior art applied in the rejection of claims 1-9 and further in view of Cheng.

With regard to claim 1, the examiner's position is as follows:

The patent to Crosbie teaches a medical tube holder apparatus 10 comprising a one-piece clamp means configured transversely to engage frictionally about the circumference of a medical tube, with opposing interlocking extremities 16 and 28 and opposing attaching means (see Figure 1) respectively adjacent each said extremity for the purpose of affixing a harness means (see Figure 8). Crosbie therefore teach appellant's device as is broadly recited in claim 1 with the exception of specifically teaching the use of naso tracheal tubes. However, Crosbie does teach that typical tube sizes includes 2.5-9.0 mm (column 2, lines 46+). ET tubes such as the White Opaque Plastic tube sold by Ohio Chemical (catalog, page 40) range in size from 2.5-9.0 mm and are used for both mouth and nose insertion. Clearly then, the Crosbie device will work with naso and mouth inserted ET tubes. Austin teach that both naso and oral ET placement is known to those of ordinary skill in the art, and that the same tube holder can be used for both. As such, and given that the Crosbie device can accommodate naso ET tube diameter, it would have been obvious to one of ordinary skill in the art to have used the Crosbie device with both naso ET and oral ET tubes.

We have carefully considered appellant's arguments supporting patentability of claim 1 as set forth on pages 21-26 of the main brief.³ However, we are not persuaded that the rejection of claim 1 is improper.

³ With regard to claims 1-9, appellant refers at various places in the main brief (see, for example, page 28) to a rejection under 35 U.S.C. § 102(b). However, there is no § 102(b) rejection of any appealed claim before us for review.

The Crosbie patent discloses a device (called a “clutch”) for holding a medical tube, particularly an endotracheal or pediatric tube (column 1, lines 20-24 and column 2, lines 46-50). Like appellant’s holder, Crosbie’s medical tube holder comprises a clamp means in the form of a clasp having opposing interlocking extremities (16, 28) as well as attaching means in the form of apertured ears (called wing members) (13, 26) for attachment to a harness-like member as shown in Figure 8 of the patent drawings. As shown in Figures 1-5 of the Crosbie patent, Crosbie’s interlocking extremities correspond to appellant’s serrated male and female locking members. Like appellant’s holder, Crosbie’s ears are integral with and extend from a body portion of the clamp means.

As disclosed in column 2, lines 44-45, of the Crosbie patent, Crosbie’s entire holder or “clutch,” as it is called, may be injection molded from a suitable polymer. As such, Crosbie’s holder is a one-piece structure and is flexible as particularly shown in Figure 8 of the patent drawings.

Furthermore, to the extent that appellant’s structure can be called an “elongated strip” (appealed claim 1, line 1), Crosbie’s tube gripping structure is likewise in the form of an elongated strip because appellant’s structure and Crosbie’s structure are shown to be generally of the same configuration. In this regard, it is significant to note that on page 6 of appellant’s specification, the strip shaped holder is expressly described as being “generally circular” (emphasis added) similar to Crosbie’s configuration.

Like appellant’s holder, the body portion of Crosbie’s clasp or clamp transversely, frictionally engages the entire of circumferential cross-section of a medical tube having a radius within a predetermined range of radii. In fact, Crosbie expressly discloses that his

holder accommodates all sizes of endotracheal and pediatric tubes (see column 1, lines 23-24 and lines 44-45).

Based on the foregoing findings and the findings made by the examiner on pages 4-5 of the supplemental answer, we agree with the examiner that the only difference between the subject matter of appealed claim 1 and Crosbie's teachings is that Crosbie lacks an express disclosure of inserting the medical tube into a patient's nasal passage. However, the recitation in claim 1 that the medical tubes are for "oral and nasal insertion" is merely a statement of intended use of the tube and thus is not germane to the patentability of the holder per se. See Loctite Corp. v. Ultraseal Ltd. 781 F.2d 861, 868, 228 USPQ 90, 94 (Fed. Cir. 1985), In re Casey, 370 F.2d 576, 580, 152 USPQ 235, 238 (CCPA 1967) and In re Lemin, 326 F.2d 437, 440, 140 USPQ 273, 276 (CCPA 1964). In any case, as noted by the examiner, Crosbie does disclose medical tube sizes (e.g., 2.5mm in line 50 of column 2) that are small enough to be capable of nasal insertion. In this regard, the Ohio Chemical catalog is cited as evidence that tubes having small diameters, such as 2.5mm, are used for nasal insertion. As the very least, therefore, Crosbie discloses that his holder will hold a tube of a size that is inherently capable of nasal insertion. Furthermore, we agree with the examiner that Austin suggests the concept of nasal intubation as an alternate to insertion via the mouth. Since the advantages of both types of intubation are known in the prior art, the selection of one or the other would have been obvious. See In re Heinrich, 268 F.2d 753, 756, 122 USPQ 388, 390 (CCPA 1959).

With regard to appellant's arguments in the paragraph bridging pages 21 and 22 of the main brief, it is clear that, in the use of Crosbie's holder, not all tube sizes will be

deformed in the manner shown at 100 in Figure 5 of Crosbie's drawings. In any case, claim 1 does not exclude such a deformation.

With further regard to the paragraph bridging pages 21 and 22 of the main brief, it is significant to observe that appellant does not argue that the claimed attaching means in claim 1 differs in any way from Crosbie's attachment ears or wings. Instead, appellant is content with arguing that his invention as a whole differs from Crosbie's medical tube holder without pointing out any differences between Crosbie's holder that the holder claimed in claim 1.

With regard to page 23 of the main brief, appellant contends that Crosbie's attachment ears are not "adjacent to" or "contiguous with" the locking members. Contrary to appellant's allegation in lines 18-22 on page 23 of the main brief, however, claim 1 was not amended to recite the "precise location" of the attaching means. In fact, claim 1 does not recite any particular location for the attaching means, let alone reciting that the attaching means is "adjacent to" or "contiguous with" the clamp means. Merely reciting that the attaching means is "integral" with the clamp means is not tantamount to a recitation that the attaching means is adjacent to or contiguous with the clamp means. In this regard, it is well established patent law that features not claimed may not be relied upon to support patentability. See In re Self, 671 F.2d 1344, 1350-1351, 213 USPQ 1, 5 (CCPA 1982) and In re Richards, 187 F.2d 643, 645, 89 USPQ 64, 66 (CCPA 1951).

We also disagree with appellant's argument on page 24 of the main brief. For the reasons discussed supra, claim 1 does not distinguish from Crosbie by reciting that the clamp means is a "strip." Furthermore, contrary to appellant's argument, the operation of Crosbie's holder is virtually the same as the operation of appellant's holder from the

standpoint that Crosbie's male and female serrated, interengaging locking members are similar to appellant's locking members and function in the same way as appellant's locking members.

Finally, appellant's arguments about nasal intubation (see pages 25-26 of the main brief) are not persuasive for the reason discussed supra. As for the argument on page 26 of the main brief, Crosbie's illustrated tube holder does have a bite block. However, claim 1 is not written in such a way to exclude a bite block. Appellant has introduced no evidence to show that Crosbie's bite block would prohibit nasal intubation. In this regard, it is well settled that arguments of counsel cannot take the place of evidence. In re Pearson, 494 F.2d 1399, 1405, 181 USPQ 641, 646 (CCPA 1974).

For the reasons discussed supra, the subject matter of claim 1 is either anticipated by Crosbie or, at the very least, obvious from the combined teachings of Crosbie, the Ohio Chemical catalog and Austin. Accordingly, we will sustain the examiner's § 103 rejection of claim 1.

We will also sustain the § 103 rejection of dependent claims 2 and 3. With particular regard to claim 3, appellant concedes on page 27 of the main brief that Crosbie discloses a "circular clamp." This does not amount to a distinction over Crosbie. The word "circular" is simply a synonym for the word "ring." Like appellant's holder, the clamping body of Crosbie's holder has a ring-like configuration to define a circular aperture for receiving the medical tube as shown, for example, in Figure 3 of the Crosbie patent. Thus, to the extent that appellant's body can be called a "ring clamp," Crosbie's clamp body may also be regarded as being a "ring clamp" because the configuration of Crosbie's clamp and the configuration of appellant's clamp are similar. Since appellant's

ring clamp is defined as one form or species of a pinch clamp (claim 3 which recites the ring clamp is dependent on claim 2 which recites the pinch clamp), it follows that Crosbie's clamp is also one form of a pinch clamp.

Appellant does not argue that the subject matter added by dependent claims 4-9 differs from Crosbie's holder. In fact, the locking members defined in claims 4 and 5 are met by Crosbie. As for claims 6-9, appellant concedes on page 28 of the main brief that Crosbie's attachment ears are also slotted. Like appellant's structure, Crosbie's attachment ears are integral with the clamping body. For these reason we will also sustain the § 103 rejection of claims 4-9.

We will not sustain the § 103 rejection of claims 19-24 and 37-48. In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a prima facie case of obviousness. See In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). This burden has not been met with respect to claims 19-24 and 37-48. The examiner has presented no explanation or rationale in support of the § 103 rejection of these claims. In fact, other than the statement of the rejection, no mention is made of these claims either in the initial answer (Paper No. 15) or in the supplemental answer (Paper No. 23).

We also will not sustain the § 103 rejection of claims 10-18 and 25-33 based on the combined teachings of Crosbie, Austin, the Ohio Chemical catalog and Cheng. Neither Cheng nor any of the other applied references, for that matter, suggests appellant's claimed c-shaped pocket as defined in claims 10-18. Furthermore, even if Crosbie's holder were modified to somehow incorporate Cheng's slot 25, the resulting

structure would not meet the terms of claims 10-18. Claims 25-33, by virtue of their dependency, are also limited to the c-shaped pocket.

Under the provisions of 37 CFR § 1.196(b), the following new grounds of rejection are entered against claims 37 through 48:

1. Claims 37 through 48 are rejected under the first paragraph of 35 U.S.C. § 112 as being based on a specification which, as filed, does not satisfy the description requirement in that paragraph.

2. Claims 41 through 44 are rejected under the second paragraph of 35 U.S.C. § 112 as being indefinite for failing to particularly point out and distinctly claim the subject matter which appellant regards as his invention.

With regard to the § 112, first paragraph, rejection, the test for determining compliance with the written description requirement in the first paragraph of § 112 is whether the disclosure in appellant's application as originally filed reasonably conveys to the artisan that appellant had possession at that time of the subject matter now claimed. In re Kaslow, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983). The content of the original specification, including the original claims, and the original drawings may be considered in determining compliance with the descriptive requirement. Id.

In the present case, there is no descriptive support in the original specification, including the original claims, for the recitation in independent claim 37 that the strip, exclusive of the interlocking extremities and the attaching means, is less than 1 centimeter thick. In fact, we find no description in the specification as filed that any part of the strip is less than 1 centimeter thick. The statement on page 7 of the specification that the "medical tube holder apparatus is of relatively small size and low profile" does

not necessarily mean that exclusive of the interlocking extremities and the attaching means, the claimed strip is less than 1 centimeter thick. For this reason alone, the disclosure as originally filed does not reasonably convey to one skilled in the art that appellant had possession of the subject matter claimed in claims 37-48 to meet the test in Kaslow.

Furthermore, we find no descriptive support in the specification as filed for the recitation in claims 41-44 that the peripheral notch will hold an auxiliary tube “without cam or shoe.” For this additional reason, claims 41-44 are based on a disclosure which, as filed, does not satisfy the description requirement in the first paragraph of § 112.

With regard to the § 112, second paragraph, rejection of claims 41-44, the meaning of a “cam” and the meaning of a “shoe” in the context used in claims 41-44 are not clear. As a result, the metes and bounds of claims 41-44 cannot be determined with a reasonable degree of precision as required in In re Venezia, 530 F.2d 956, 958, 189 USPQ 149, 151 (CCPA 1976).

In summary, the examiner’s decision rejecting appealed claims 1 through 33 and 37 through 48 under 35 U.S.C. § 103 is affirmed with respect to claims 1 through 9, but is reversed with respect to claims 10 through 33 and 37 through 48. In addition, new grounds of rejection have been entered against claims 37 through 48 pursuant to 37 CFR § 1.196(b).

In addition to affirming the examiner's rejection of one or more claims, this decision contains new grounds of rejection pursuant to 37 CFR § 1.196(b) (amended effective Dec. 1, 1997, by final rule notice, 62 Fed. Reg. 53,131, 53,197 (Oct. 10, 1997), 1203 Off. Gaz. Pat. & Trademark Office 63, 122 (Oct. 21, 1997)). 37 CFR § 1.196(b)

provides, "[a] new ground of rejection shall not be considered final for purposes of judicial review."

Regarding any affirmed rejection, 37 CFR § 1.197(b) provides:
(b) Appellant may file a single request for rehearing within
two months from the date of the original decision

37 CFR § 1.196(b) also provides that the appellant, WITHIN TWO MONTHS
FROM THE DATE OF THE DECISION, must exercise one of the following two options
with respect to the new ground of rejection to avoid termination of proceedings (37 CFR
§ 1.197(c) as to the rejected claims:

- (1) Submit an appropriate amendment of the claims so
rejected or a showing of facts relating to the claims so
rejected, or both, and have the matter reconsidered by the
examiner, in which event the application will be remanded
to the examiner
- (2) Request that the application be reheard under
§ 1.197(b) by the Board of Patent Appeals and
Interferences upon the same record

Should the appellant elect to prosecute further before the Primary Examiner
pursuant to 37 CFR § 1.196(b)(1), in order to preserve the right to seek review under
35 U.S.C. §§ 141 or 145 with respect to the affirmed rejection, the effective date of the
affirmance is deferred until conclusion of the prosecution before the examiner unless, as a
mere incident to the limited prosecution, the affirmed rejection is overcome.

If the appellant elects prosecution before the examiner and this does not result in
allowance of the application, abandonment or a second appeal, this case should be
returned to the Board of Patent Appeals and Interferences for final action on the affirmed
rejection, including any timely request for reconsideration thereof.

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No time period for taking any subsequent action in connection with this appeal
may be extended under 37 CFR § 1.136(a).

AFFIRMED-IN-PART/37 CFR § 1.196(b)

HARRISON E. MCCANDLISH)	
Senior Administrative Patent Judge)	
)	
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)	BOARD OF PATENT
JOHN P. MCQUADE)	APPEALS AND
Administrative Patent Judge)	INTERFERENCES
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HEM/sld

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